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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,061	07/31/2003	Robert E. Richard	02-321 (4010/41)	9972
27774 7590 06/09/2011 MAYER & WILLIAMS PC 251 NORTH AVENUE WEST Suite 201 WESTFIELD, NJ 07090				
EXAMINER				
SIMMONS, CHRIS E				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
06/09/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/632,061

**Applicant(s)**

RICHARD ET AL.

**Examiner**

CHRIS SIMMONS

**Art Unit**

1612

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 12 May 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.  
NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-9, 11-20 and 23-27.  
Claim(s) withdrawn from consideration: 28 and 29.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Patricia A Duffy/  
Primary Examiner, Art Unit 1645

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1-7, 9, 11-20 and 23-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al in view of Ruckenstein et al., the combination taken further in view of Hossainy et al., as evidenced by Reference Polymer Properties.

Applicant argues that Hossainy does not teach or suggest that a block of the methyl acrylate units would be suitable as an elastomeric block in a block (or graft) copolymer. This deficiency is not made up for by Pinchuk or Ruckenstein, according to applicant. The examiner does not find this argument persuasive. As outlined in the August 2010 Office action at pages 3 and 6, Pinchuk discloses the combination of rubbery and hard block copolymers for incorporation in a coating for implantable devices, Ruckenstein discloses grafting of copolymers and Hossainy discloses the rubbery/elastomeric poly(methyl acrylate) as a polymer suitable for incorporation in a coating for drug-releasing implantable devices. Accordingly, applicant's arguments are not found to be persuasive.

Applicant further argues Hossainy does not teach or suggest a polymeric release region comprising an acrylic graft copolymer that controls the release of therapeutic agent upon administration to a patient as claimed. In this regard, Hossainy teaches that acrylates, including copolymers of methyl acrylate, may be useful as a primer layer (see paragraphs [0031] through [0036]), but not as a layer for controlling release. The examiner does not find this argument to be persuasive. First, the examiner agrees that Hossainy teaches that acrylates, including copolymers of methyl acrylate, may be useful as a primer layer. The examiner adds that the primer, reservoir, and barrier layers can be made up of the same polymers - see Hossainy at [0014] and [0070]. Since the barrier layer controls the release of the active ingredients and it can be made up of copolymers of methyl acrylate, then Hossainy discloses copolymers of methyl acrylate as suitable for use in a polymeric coating for controlling release of active ingredients.

Applicant argues Hossainy, Pinchuk and Ruckenstein neither teach nor suggest that acrylates, including copolymers of methyl acrylate, can be used in block copolymers and because Hossainy, Pinchuk and Ruckenstein neither teach nor suggest that acrylates, including copolymers of methyl acrylate, can be used in a layer for controlling release, it is not prima facie obvious to employ such materials in the block copolymer of Pinchuk, much less so in a graft copolymer like that claimed. Applicant adds Pinchuk teaches polyolefins for use as such blocks, which are remote from polyacrylates such as poly(methyl acrylate). The examiner does not find these arguments persuasive. First, the examiner notes the rejection is based on a combination of references, any alleged deficiency in one is remedied by its combination with the other references. Although Pinchuk prefers polyolefins for use as elastomeric block copolymer, the prior art when combined suggest poly(methyl acrylate) for use in the polymeric coating of an implantable device as outlined in the August 2010 Office action.

Applicant argues that the copolymer of Pinchuk does not contain functional monomers as described in Ruckenstein. Examiner does not find this argument to be persuasive as it is irrelevant whether Pinchuk teaches functional monomers.

Applicant argues that Hossainy, Pinchuk and Ruckenstein do not teach that graft architecture can be substituted for block copolymer architecture. In fact, Ruckenstein teaches that "it is more difficult to prepare graft copolymers than block copolymers" (page 2, lines 23- 24). The examiner does not find this argument to be persuasive as the rejection is not based on substituting graft architecture for block copolymer architecture.

Claim 8 stands rejected under 35 USC 103(a) as being unpatentable over Pinchuk et al., Ruckenstein et al. and Hossainy et al. as evidenced by Reference Polymer Properties, the combination taken further in view of Williams. The rejection is maintained for reasons outlined in the August 2010 and March 2011 Office actions.

/C. S./  
Examiner, Art Unit 1612